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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/271,411	03/17/1999	M. ALLEN NORTHRUP	22660-0009P1	4121
20350 7590 10/18/2007 TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834			EXAMINER RIGGS II, LARRY D	
			ART UNIT 1631	PAPER NUMBER
			MAIL DATE 10/18/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/271,411	Applicant(s) NORTHRUP ET AL.	
	Examiner Larry D. Riggs II	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 45-55, 57, 58, 60 and 62-71 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 45-55, 57, 58, 60 and 62-71 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 March 1999 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The instant application has been transferred to Larry D. Riggs II in Art Unit 1631.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114 was filed in this application after a decision by the Board of Patent Appeals and Interferences, but before the filing of a Notice of Appeal to the Court of Appeals for the Federal Circuit or the commencement of a civil action. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 01 August 2007 has been entered.

Claims

Cancellation of claim 59 and 61 are acknowledged in the amendment filed 01 August 2007. Claims 45-55, 57, 58, 60 and 62-71 are pending.

Claim Rejections - 35 USC § 103

The rejection of claims 45-50, 52-55, 57, 58, 60 and 62-70 under 35 U.S.C. 103(a) over Handique et al. (US 6,130,098) in the Office action mailed 09 June 2004 is withdrawn in view of the amendment filed 01 August 2007.

The rejection of claims 45-50, 52-55, 57, 58, 60 and 62-70 under 35 U.S.C. 103(a) over Handique et al. (US 6,130,098) taken in view of Wilding et al. (US 5,587,128) or alternatively, Wilding et al. (US 5,587,128), taken in view of Handique et al. (US 6,130,098) in the Office action mailed 09 June 2004 is withdrawn in view of the amendment filed 01 August 2007.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 45-50, 52-55, 57 and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Handique et al. in view of Wilding et al. and in view of Ramsey.

The instant claims are drawn to an apparatus and method for analyzing a sample comprising a body, reaction chamber, separation region, transition region connecting said chamber and channel that is thermally isolated, optically monitoring said reaction chamber for reaction product, a valve in said transition region, opening said valve in said transition region, injecting a plug of reaction product into separation region, detecting said reaction product and electrodes coupled to said body.

The abstract of Handique et al. discloses the central invention as being directed to the movement and mixing of microdroplets through microchannels in devices with reaction chambers, electrophoresis modules, etc. These elements are also summarized in column 3, line 49, through column 4, line 32, which includes various reaction and analysis practices. The use of electrodes positioned in a channel so as to move liquid when a potential is applied is disclosed in column 7, line 53, through column 8, line 44, which also described flow constricting means in such channels. Various other flow constricting elements are present in the channels as noted in column 10, lines 57-65. In column 13, lines 19-34, a device of the invention includes reaction chamber, channels which serve as transition regions connecting said chamber, and an electrophoresis modules which is a separation region where migration data is detected regarding electrophoretic separation. Such a separation via electrophoresis is further detailed in

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column 21, lines 35-67, including optics for detecting bands from said electrophoresis separation region. These devices are microfabricated with the regions etc. therein reasonably interpreted as enclosed as described in column 3, line 65, through column 4, line 10, in an integrated system. Thermal conduction is limited in the device so that droplet movement can be controlled as noted in column 8, lines 1-9, via differential heating. The practice of a two part device with electrical pads as needed in a second or appliance type of element is disclosed in column 13, lines 49-59. The presence of heaters in the substrate are also described in a two part device as noted in column 18, line 40, through column 19, line 44. Side channels with flow control may also be utilized in the device of the invention as disclosed in column 14, line 24, through column 15, line 19.

Handique et al. as applied to claims 45-50, 52-55, 57 and 58, does not utilize polymeric materials molded for such device production or electrodes screen-printed on the body.

Wilding et al. also describes devices and production thereof for microscale reaction~analysis practice and has previously been cited in the prosecution history of this application as citing reaction chamber, transition region, and separation region elements for such devices and therefore is of the same subject matter type as the above noted Handique et al. invention. In Wilding et al. in column 7, lines 22-38, microfabrication of devices of this microscale or mesoscale type is suggested and motivated to be equivalently usable when made by silicon photolithography wherein the silicon may be polysilicon, polyimide, etc. as well as produced via plastic molding. Thus,

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a reasonable expectation of success in producing such devices and thus describing the devices per se is set forth for polymeric molding of devices of this type.

Handique et al. in view of Wilding et al. as applied to claims 45-50, 52-55, 57 and 58 above do not show electrodes screen-printed on the body.

Ramsey provides an apparatus and method for performing microfluidic manipulations for chemical analysis and synthesis. Ramsey shows electrodes on the microfabricated device through photolithographic patterning and metal deposition, in column 18, lines 1-3.

Claim 51 is rejected under 35 U.S.C. 103(a) as being unpatentable over Handique et al. in view of Wilding et al. in view of Ramsey as applied to claims 45-50, 52-55, 57 and 58 above, and further in view of Burns et al.

The instant claims are drawn to an apparatus and method for analyzing a sample comprising a body, reaction chamber, separation region, transition region connecting said chamber and channel that is thermally isolated, optically monitoring said reaction chamber for reaction product, a valve in said transition region, opening said valve in said transition region, injecting a plug of reaction product into separation region, detecting said reaction product and electrodes coupled to said body.

Handique et al., Wilding et al. and Ramsey as applied to claims 45-50, 52-55, 57 and 58 above, do not show pneumatically controlled membrane valves.

Burns et al. provides a chip-based isothermal amplification device and method. Burns shows actuating forces of liquid pushing a diaphragm against a valve seat to form

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a diaphragm valve, (see specification, page 12, line...this valve may be an on-off valve, such as a pinch-off valve, a membrane valve or the like), see column 44, lines 9-40.

Claims 60 and 62-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Handique et al. in view of Wilding et al.

The instant claims are drawn to an apparatus and method for analyzing a sample comprising a body, reaction chamber, separation region, transition region connecting said chamber and channel that is thermally isolated, optically monitoring said reaction chamber for reaction product, a valve in said transition region, opening said valve in said transition region, injecting a plug of reaction product into separation region, detecting said reaction product and electrodes coupled to said body.

The abstract of Handique et al. discloses the central invention as being directed to the movement and mixing of microdroplets through microchannels in devices with reaction chambers, electrophoresis modules, etc. These elements are also summarized in column 3, line 49, through column 4, line 32, which includes various reaction and analysis practices. The use of electrodes positioned in a channel so as to move liquid when a potential is applied is disclosed in column 7, line 53, through column 8, line 44, which also described flow constricting means in such channels. Various other flow constricting elements are present in the channels as noted in column 10, lines 57-65. In column 13, lines 19-34, a device of the invention includes reaction chamber, channels which serve as transition regions connecting said chamber, and an electrophoresis modules which is a separation region where migration data is detected regarding

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electrophoretic separation. Such a separation via electrophoresis is further detailed in column 21, lines 35-67, including optics for detecting bands from said electrophoresis separation region. These devices are microfabricated with the regions etc. therein reasonably interpreted as enclosed as described in column 3, line 65, through column 4, line 10, in an integrated system. Thermal conduction is limited in the device so that droplet movement can be controlled as noted in column 8, lines 1-9, via differential heating. The practice of a two part device with electrical pads as needed in a second or appliance type of element is disclosed in column 13, lines 49-59. The presence of heaters in the substrate are also described in a two part device as noted in column 18, line 40, through column 19, line 44. Side channels with flow control may also be utilized in the device of the invention as disclosed in column 14, line 24, through column 15, line 19.

Handique et al. as applied to 60 and 62-70, does not optically monitor the reaction chamber for product.

Wilding et al. also describes devices and production thereof for microscale reaction~analysis practice and has previously been cited in the prosecution history of this application as citing reaction chamber, transition region, and separation region elements for such devices and therefore is of the same subject matter type as the above noted Handique et al. invention. In Wilding et al. in column 7, lines 22-38, microfabrication of devices of this microscale or mesoscale type is suggested and motivated to be equivalently usable when made by silicon photolithography wherein the silicon may be polysilicon, polyimide, etc. as well as produced via plastic molding. Thus,

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a reasonable expectation of success in producing such devices and thus describing the devices per se is set forth for polymeric molding of devices of this type. Wilding et al. also includes optical monitoring of reaction product before entering into the separation region, in column 19, lines 31-37.

Claim 70 is rejected under 35 U.S.C. 103(a) as being unpatentable over Handique et al. in view of Wilding et al. as applied to claims 60 and 62-70 above, and further in view of Manz et al.

The instant claims are drawn to an apparatus and method for analyzing a sample comprising a body, reaction chamber, separation region, transition region connecting said chamber and channel that is thermally isolated, optically monitoring said reaction chamber for reaction product, a valve in said transition region, opening said valve in said transition region, injecting a plug of reaction product into separation region, detecting said reaction product and electrodes coupled to said body.

Handique et al. in view of Wilding et al. as applied to claims 60 and 62-70 above, do not show separating product by isoelectric focusing.

Manz et al. provide a device and method for the electrophoretic separation of fluid substance mixtures. Manz shows separation of product by isoelectric focusing in the first phase of separation, see column 5, lines 28-38.

It would have been obvious to someone of ordinary skill in the art at the time of the instant invention to produce or practice the electrode/voltage invention of Handique

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et al. with various microfabricated polymeric materials as equivalent as described in Wilding et al., patterning electrodes on the microfabricated device described in Ramsey, fabricating and using a diaphragm valve described in Burns et al, and separating product with isoelectric focusing as described in Manz et al. to result in a reasonable expectation of success to practice the device and/or combination of device with appliance substrate of the instant invention or production thereof.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry D. Riggs II whose telephone number is 571-270-3062. The examiner can normally be reached on Monday-Thursday, 7:30AM-5:00PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/LDR/
Larry D. Riggs II
Examiner, Art Unit 1631

/John S. Brusca/
Primary Examiner
Art Unit 1631